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jc780 U.S. PTO 04/25/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: SPEN-15

Applicant: Paul A. Spence

Title: SUPPLEMENTAL HEART PUMP METHODS AND SYSTEMS FOR SUPPLEMENTING BLOOD THROUGH THE HEART

jc530 U.S. PTO 09/557562 04/25/00

CERTIFICATE OF MAILING BY EXPRESS MAIL - 37 CFR 1.10

'Express Mail' mailing label number: EL328380151US
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I certify that this paper or fee (along with the enclosures noted herein) is being deposited with the United States Postal Service 'Express Mail Post Office to Addressee' service under 37 CFR 1.10 on the above date and is addressed to the Assistant Commissioner for Patents, Washington, D C. 20231.

By. Heath R. Bandy (person mailing paper)

UTILITY PATENT APPLICATION TRANSMITTAL

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

This is a request for filing, under 37 CFR § 1.53(b), a(n):

- ☒ **Original (non-provisional) application.**
- ☐ Divisional of prior application Serial No. __, filed on __.
- ☐ Continuation of prior application Serial No. __, filed on __.
- ☐ Continuation-in-part of prior application Serial No. __, filed on __.

PRELIMINARY AMENDMENT/CALCULATION OF FEES

- ☐ Please cancel claims __ without prejudice, and prior to calculating the fees. __ total claim(s), of which __ is(are) independent, is(are) pending after the amendment.
- ☐ Please enter the enclosed preliminary amendment identified below prior to calculating the fees. __ total claim(s), of which __ is(are) independent, is(are) pending after the amendment.
- ☒ **The Fees are Calculated as Follows:**

Fee	Number of Claims·	In Excess of:	Extra:	At Rate·	Amount:
Total Claims	19	20	0	$18	$0 00
Independent Claims	5	3	2	$78	$156 00
MULTIPLE DEPENDENT CLAIM FEE					
BASIC FEE					$690 00
TOTAL OF ABOVE CALCULATIONS					$846.00
REDUCTION BY 50% FOR FILING BY SMALL ENTITY					$423.00
TOTAL					$423.00

ENCLOSURES

☒ **Utility Patent Application Transmittal Form (in duplicate) containing Certificate of Mailing By Express Mail Under 37 CFR 1.10.**

☒ **Return Postcard.**

APPLICATION PAPERS

☒ **Utility Patent Application, with: cover sheet, 23 page(s) specification (including 19 total claim(s), of which 5 is(are) independent), and 1 page(s) abstract.**

☒ **Drawings: 4 sheet(s) of informal drawings (5 total figure(s)).**

☐ Microfiche Computer Program (Appendix).

☐ Nucleotide and/or Amino Acid Sequence, including (all are necessary): Computer Readable Copy, Paper Copy (identical to computer copy), and Statement verifying identity of copies.

☒ **An Executed Declaration, Power of Attorney and Petition Form.**

☐ Copy of Executed Declaration, Power of Attorney and Petition Form from prior application identified above.

☐ Certified Copy of priority document(s) identified as attached above.

ADDITIONAL PAPERS

☐ Assignment to __, Recordation Cover Sheet (Form PTO-1595)

☒ **Verified Statement to Establish Small Entity Status under 37 CFR 1.9 and 1.27.**

☐ Preliminary Amendment (to be entered prior to calculation of fees)

☐ Information Disclosure Statement, __ sheet(s) Form PTO-1449, __ U.S. Patent Reference(s), __ Foreign Patent Reference(s) and __ Other Reference(s)

☐ Other: __

CHECKS

☒ **A Check of $423.00 for the filing fee.**

☐ A Check of __ for the assignment recording fee.

DEPOSIT ACCOUNT AUTHORIZATION

☐ Please charge Deposit Account No. 23-3000 in the amount of __.

☒ **The Commissioner is authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required during the entire pendency of the application, or credit any overpayment, to Deposit Account No. 23-3000. A duplicate of this transmittal is attached.**

☐ THE PAYMENT OF FEES IS BEING DEFERRED.

Respectfully Submitted,

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Applicant or Patentee:	**Paul A. Spence**
Attorney's Docket No.	**SPEN-15**
Serial or Patent No. :	**Unknown**
Filed or Issued:	**Herewith**
For:	**SUPPLEMENTAL HEART PUMP METHODS AND SYSTEMS FOR SUPPLEMENTING BLOOD THROUGH THE HEART**

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled **Supplemental Heart Pump Methods and Systems for Supplementing Blood Through the Heart** described in:

[XX] the specification filed herewith

[ ] application serial no. _____, filed _____, issued _____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(a).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

[X] no such person, concern, or organization

[ ] persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME: _____

ADDRESS: _____

[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time

of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of sole or first inventor
(given name, family name) Paul A. Spence

Inventor's signature *Paul Spence* Date *April 21/00*

Address of Inventor 5818 Orion Drive, Louisville, Kentucky 40222

Express Mail No.: EL328380151US

APPLICATION FOR UNITED STATES PATENT

Title: **SUPPLEMENTAL HEART PUMP METHODS AND SYSTEMS FOR SUPPLEMENTING BLOOD THROUGH THE HEART**

Applicant: Paul A. Spence

SPECIFICATION

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Atty Docket No.: SPEN-15

SUPPLEMENTAL HEART PUMP METHODS AND SYSTEMS FOR SUPPLEMENTING BLOOD THROUGH THE HEART

Field of the Invention

The present invention generally relates to devices and methods for assisting heart function and, more particularly, devices and methods intended to supplement the natural blood pumping ability of a patient's native heart.

Background of the Invention

Two major options exist for treating a weakened or diseased heart. A totally artificial heart may be implanted or a heart transplant may be performed, or a heart assist device may be used to supplement the function of the patient's natural heart to achieve a total blood flow through the heart which is acceptable. Most of the development in this area has been directed toward completely implantable heart replacements and significantly invasive heart assist devices which are bulky and complicated. There will always be some need for such devices, however, for every

patient on the transplant list who may need a totally artificial heart there are fifty less serious cases of congestive heart failure in which the patient survives on other medical therapy. Unfortunately, the conventional medical therapies may not be sufficient to provide a high quality of life for the patient. Completely artificial hearts are also risky due to biological compatibility problems, blood clotting, manufacturing problems and regulatory issues. The surgical operation to install artificial hearts is very complex and, after installation, significant maintenance and follow-up is necessary.

Many patients will succeed with a partial heart assist which increases cardiac output by 20% to 50%. Such a device would well serve patients with idiopathic cardiomyopathy, ischemic cardiomyopathy, ischemic mitral regurgitation and progressive mitral regurgitation. In fact, a partial heart assist device may be completely sufficient for many potential transplant patients. Early installation of a partial heart assist device could unload the heart and prevent the development of congestive heart failure in patients with declining left ventricular function. If the hearts of these patients are partially unloaded with a suitable device, this could entirely avoid the need for surgery. Other patients may be too old for invasive surgery, but could lead higher quality lives with a suitable partial heart assist device. In all patients, aortic and mitral insufficiency (that is, volume overload conditions) are well-tolerated for many years until the heart begins to dilate. It may be desirable to allow these valves to leak to some extent,

while unloading the heart and preventing dilation and the need for future surgery.

A large number of patients with ischemic coronary artery disease continue to have pain when they are undergoing maximal drug therapy. This maximal therapy is defined as the point when heart failure symptoms occur. With a suitable heart assist device, drug doses may be increased further while supporting the patient's heart with a partial heart assist device. Unloading dilated hearts with a partial or supplemental heart assist device may also reduce the risk of fatal arrhythmia and may be an effective adjunct for patients with defibrillators. It may also increase the amount of drug that can be effectively administered for arrhythmia as many of these agents depress contractility. Partial heart assist devices may also be useful after massive infarction to unload the heart and prevent unfavorable remodeling.

Ever since its introduction, the pacemaker has been widely accepted and very successful. The pacemaker is relatively simple to insert and does not require a major surgical operation. It is located superficially in a subcutaneous area of the patient's chest and is not regarded as highly invasive. As the market for pacemakers has grown, additional features have been added, such as defibrillators and cardioverters. Due to their simplicity and reliability, pacemakers are now inserted for even a suspicion of a potentially dangerous arrhythmia.

It would be desirable to provide a partial assist device or system along with associated methods which provide effective assistance

with cardiac output as well as simplicity of design, ease of implantation, low cost and reliability. In essence, it would be desirable to provide a system and methods which combine the intentions of past heart assist devices with the simplicity, reliability, minimal invasiveness and other desirable attributes of a pacemaker-type device. A partial assist device which is only slightly more complex to insert than a pacemaker and that is as reliable, cost effective and as versatile as a pacemaker would increase the quality of life for many additional patients.

Summary of the Invention

In one aspect, therefore, the present invention contemplates a device requiring only a small pocket made subcutaneously over the patient's chest, such as in the subclavicular region, as in a pacemaker, for housing a blood pump. Preferably, the size, shape and implant location would be similar to a pacemaker. The inflow for the pump is provided by a catheter or other conduit which is inserted into the left side of the heart, such as the left atrium, either by a small thoracotomy, sternotomy or by an endoscopic approach using ports placed in the chest. The cannula will then be passed out of the chest between the ribs and attached to the pump. The outflow from the pump may be completed by sewing a graft from the pump outlet to an artery in the shoulder area, such as an axillary artery, or by connecting a cannula between the pump and the shoulder artery. In short, oxygenated blood will be pumped from the left atrium of the heart to the shoulder artery and into the aorta. Various manners of powering the pump may be

provided, such as by using a transcutaneous power supply with internal and external power coils, as known in the medical art, or other power supply either within the patient's body or outside the patient's body. An external energy source may be connected to the patient by a harness or belt. As another aspect of the invention, a reliable connection and alignment system is provided for the external portion of the power supply.

In a second aspect of the invention, the goal is to eliminate the intrathoracic part of the procedure. In this operation, the inflow cannula will pass from the axillary vein down the subclavian vein into the right atrium of the heart and across the septum in the left atrium. Blood will be withdrawn from the left atrium retrograde, up the subclavian vein inside the cannula and pumped into the axillary artery or another shoulder artery. The entire procedure may be accomplished from the same subclavicular incision. To augment blood flow, additional drainage catheters may be added from the opposite side of the chest or from the ipsilateral or contralateral neck veins. To simplify this procedure so that maximal blood flow is achieved, it may be easier to provide a large left atrial drainage cannula that occludes the right or left subclavian vein. In this case, however, the patient's arm may swell if the patient is not provided with a manner of returning blood from the arm. For this purpose, a second cannula, or a separate portion or orifice of the inflow cannula, may be used to pump the venous return from the arm around the obstruction and into the right side of the heart. As another alternative, the blue blood, or venous return from the arm may be mixed with the red blood or oxygenated blood from the left side of the heart

and this mixture may be pumped back into the axillary artery. Provided that the left atrial blood is fully saturated, up to 25% venous blood could be mixed with the oxygenated blood or red blood from the left atrium before desaturation occurs.

Each of the procedures performed with products of the invention would require only a small incision in the shoulder area comparable to the size of a pacemaker or defibrillator. A pocket would be made for the pump and, for example, another pocket for a power coil or internal portion of a transcutaneous power supply. The subclavian vein would be cannulated for access to the left atrium of the heart and the outflow of the pump would be connected for fluid communication with the axillary artery or another shoulder artery. All of these portions of the procedure may be accessed through the same incision.

Various additional possibilities for the system and methods of this invention exist, including: 1) the cannulation points may vary, such as by making the artery or vein cannulation points anywhere in the shoulder or neck area, and not specifically in the subclavian vein and axillary artery; 2) when the left atrium is cannulated, the cannula will likely pass between the ribs, however, the cannula could also pass below the ribs, such as through the diaphragm, or above the ribs, such as out the thoracic inlet; 3) the left ventricle may be cannulated instead of the left atrium as a source of oxygenated blood; 4) the pump may be located inside or outside the chest or abdomen and not necessarily in a subcutaneous pocket on the outside of the chest or abdomen; 5) the pump may be implanted in the groin area of

the patient and may draw blood from the left atrium or ventricle and return it to the groin area arteries either to the femoral arteries or via a retroperitoneal incision to the illiac arteries; 6) the pump may be located in a tube or in a separate unit and may be of any type and shape; 7) preferably run continuously and in a highly energy efficient manner; and 8) to shut down the system, a cannula associated with the device may be clamped or partly or entirely removed from the patient.

Additional modifications, substitutions, features and advantages of the invention will become more readily apparent to those of ordinary skill in the art upon review of the following detailed description of the presently preferred embodiments in conjunction with the the accompanying drawings.

Brief Description of the Drawings

Figure 1 is a schematic view of a patient with a supplemental heart pump device installed to pump blood from the left atrium to a shoulder artery.

Figure 1A is an assembled, partial cross-section showing the power supply illustrated in exploded form in Fig. 1.

Figure 2 is a schematic illustration similar to Figure 1, but illustrating an alternative configuration of a supplemental heart pump system.

Figure 3 is an enlarged view of the shoulder region of a patient showing another alternative supplemental heart pump system.

Figure 4 is a fragmented view of the shoulder region of the patient illustrating another alternative supplemental heart pump system.

Figure 5 is a schematic view of a patient with another alternative supplemental heart pump system.

Detailed Description of the Preferred Embodiments

Figure 1 illustrates a patient 10 having a heart 12, shown in longitudinal cross section, coupled with a supplemental assist device or system 14. System 14 comprises a pump 16 which may be implanted in a small pocket made subcutaneously over the patient's chest, such as in the subclavicular region as shown in the drawing. This is a similar implantation procedure to conventional pacemakers. Pump 16 is coupled with a control 17 and a suitable electric power supply 18. Pump 16 and control 17 may be constructed in various manners known in the art, for example, as a centrifugal pump or a screw type pump. Some more specific types of pumps are disclosed in U.S. Patent Nos. 5,344,443; 5,941,813; and 5,947,892. Pump 16 may reside directly within one of the cannulas or conduits of system 14. Power supply 18 may be an implanted power supply or a power supply partially or wholly external to the patient. One particularly desirable power system comprises a transcutaneous power supply using a power coil which is periodically charged from outside the body to continuously operate pump 16. This system is discussed further below. Pump 16 is coupled with an inflow catheter 20 which extends through the heart, such as through the right atrium and septum, and into

the left atrium 22. Blood is withdrawn from the left atrium 22 by pump 16 and discharged into catheter or conduit 24 which is connected for fluid communication with an artery in the shoulder region, such as axillary artery 26.

As further illustrated in Figures 1 and 1A, power supply 18 most preferably comprises a first coil or power supply portion 19 implanted within the body of patient 10, such as in the lower abdominal region, and a second coil or power supply portion 21 positioned outside the patient's body. Second coil 21 may be in the form of a pack carried on a belt 23 worn by patient 10. In accordance with another inventive aspect, second coil 21 includes a first alignment element 25 and a second alignment element 27 is carried by an adhesive pad 29 affixed to the skin of patient 10. As further shown in Figure 1, a power lead 31 is connected between first coil 19 and pump 16 for supplying electrical power to operate pump 16. Periodically, electrical power is transferred between second coil 21 and first coil 19 such that first coil 19 can deliver stored electrical power to pump 16. As one example, such a system may take the form of the one disclosed in U.S. Patent No. 5,704,891, the disclosure of which is fully incorporated herein by reference. Such systems may allow second coil 21 to be removed from the patient for a period of time, such as during physical activity.

Figure 2 illustrates an alternative heart assist pump system 14' comprising a pump 16 and respective inflow and outflow catheters or conduits 20, 24 as in the embodiment shown in Figure 1. In this

embodiment, like reference numerals refer to like elements with the first embodiment. In this embodiment, however, catheter 20 is installed through the axillary vein 21 and is directed into the heart 12 through the right atrium and septum and again into the left atrium 22. Conduit or catheter 24 is again coupled for fluid communication with the axillary artery 26 as in the embodiment of Figure 1. In both embodiments, blood is withdrawn from the right atrium through conduit 20 and discharged into a suitable artery, such as the axillary artery 26. As another alternative shown in Figure 2, pump 16 may instead be coupled between left atrium 22 and an artery in the patient's lower body, such as a femoral artery 30.

Figure 3 illustrates another alternative heart assist device system 32 in which like reference numerals indicate like elements with Figures 1 and 2. In this embodiment, system 32 again includes conduits or catheters 20, 24 for respectively providing inflow and outflow of blood. This embodiment counteracts the potential obstruction created by conduit or catheter 20 in the axillary vein 21 by providing a separate set of conduits 34, 36. Specifically, in this embodiment a first pump 38 withdraws blood from the left atrium 22 through catheter or conduit 20 and discharges this blood through catheter or conduit 24 into axillary artery 26. A second pump 40, which may be superimposed on pump 38 in a pancake fashion as shown, withdraws blood from axillary vein 21 through conduit 36 and discharges this blood into conduit or catheter 34 to the right side of heart 12. This allows blood from the patient's arm to bypass the obstruction created by catheter or conduit 20 and therefore prevent any potential

swelling problems of the patient's arm. It will be appreciated that the pumps associated with this invention may take many different forms including, but not limited to compact centrifugal pumps and peristaltic pumps.

Figure 4 illustrates another alternative solution to the obstruction problem referred to above. In this embodiment, pump 16 includes a conduit or catheter 24 which again provides outflow of blood to axillary artery 26. However, in this embodiment the inflow catheter or conduit 42 is connected to both the left side of the heart (not shown) through a catheter segment or branch 42a and also fluidly coupled to an opposite side of the axillary vein 21, for example, through a second catheter portion or branch 42b. This second catheter branch 42b may comprise an orifice in branch 42a. Here, the intention is to mix the blue blood or nonoxygenated blood returning from the patient's arm through axillary vein 21 and catheter branch 42b with the red blood or oxygenated blood being withdrawn from the left side of the patient's heart (not shown). Up to 25% of the venous blood or nonoxygenated blood may be mixed with the red blood before desaturation occurs. In this embodiment, the mixture of blood travels through conduit or catheter 42 and into pump 16 before being discharged through conduit or catheter 24 into axillary artery 26.

Figure 5 illustrates a system similar to the system shown in Figure 1 with like reference numerals indicating like elements between the two embodiments. Power supply 18 may be the transcutaneous power

supply illustrated in Figure 1, or another transcutaneous system, fully implanted power supply system, or fully external power supply system. The only other difference between these two embodiments, as illustrated in Figure 5, is the provision of a return conduit 50 coupled with system 14'. Return conduit 50 may lead to various locations of the system to provide a cleansing or rinsing function. For example, as there may be pumps 16 which include stagnant interior portions susceptible to accumulating blood clots, return conduit 50 is provided between an output 52 of pump 16 and an input 54 coupled with a suction side of pump 16 for returning a small portion of the blood output to the pump and, more particularly, to any portion or portions of the interior of pump which may be susceptible to stagnation and blood clot formation. Different pump configurations will have different areas of potential stagnation and these areas may be determined by those of ordinary skill in the art depending on the particular internal pump configuration. It is anticipated that return conduit 50 will preferably be sized and coupled with pump 16 such that only 5-10% of the blood output will be returned to pump 16 for this rinsing or cleaning function of any stagnant internal pump area. As necessitated by the particular pump system, additional return outputs may be provided depending on the number of system areas necessitating this function. One other example for the use of a return conduit in system 14' would be to lead a return conduit into the left atrium 22 to rinse an outside or inside end portion of conduit or catheter 20 to prevent clogging at this location.

While the present invention has been illustrated by a description of preferred embodiments and while these embodiments have been described in some detail, it is not the intention of the Applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The various features and concepts of the invention may be used alone or in numerous combinations depending on the needs and preferences of the user. As one example, one or more conduits may be integrated into a single conduit structure having multiple flow paths. This has been a description of the present invention, along with the preferred methods of practicing the present invention as currently known. However, the invention itself should only be defined by the appended claims, wherein I claim:

1. A method of supplementing the blood flow from the heart of a patient using a pump assist system, the method comprising:

directing a first conduit into the left side of the heart,

coupling a second conduit in fluid communication with a superficial artery of the patient,

connecting a pump between the first and second conduits,

implanting the pump in a superficial, subcutaneous area of the patient,

connecting an electrical power supply to the pump,

suctioning blood from the left side of the heart through the first conduit and into the pump, and

expelling the blood from the pump into the second conduit and the superficial artery.

2. The method of claim 1, wherein the step of directing a first conduit into the left side of the heart further comprises:

directing the first conduit into a superficial vein and transeptally through the heart.

3. The method of claim 1, wherein the step of implanting the pump further comprises:

implanting the pump superficially and subcutaneously in the chest region of the patient.

4. The method of claim 1, wherein the step of connecting a power supply further comprises:

connecting a transcutaneous power supply by implanting a first portion of said power supply superficially and subcutaneously in the patient and removably coupling a second portion of said supply outside the patient.

5. The method of claim 1, wherein the first conduit is introduced into the left side of the heart through the axillary vein of the patient.

6. The method of claim 5, further comprising:

directing a third conduit into the axillary vein,

directing a fourth conduit into the axillary vein, and

pumping blood from the third conduit to the fourth conduit and into the right side of the heart to bypass an obstruction formed by the first conduit.

7. The method of claim 1, wherein the second conduit is directed into the axillary artery of the patient.

8. The method of claim 2, wherein the first conduit includes first and second branches with the first branch communicating with the left side of the heart and the second branch fluidly communicating with the superficial vein, and

the suctioning step further comprises suctioning blood from the left side of the heart through the first branch and suctioning blood from the superficial vein through the second branch, and

the expelling step further comprises expelling the blood from the first and second branches into the second conduit.

9. The method of claim 1 further comprising:

returning a portion of the expelled blood to the pump before the portion of expelled blood reaches the superficial artery.

10. The method of claim 1 further comprising:

returning a portion of the expelled blood to another portion of the pump assist system to perform a rinsing function.

11. A method of supplementing the blood flow from the heart of a patient using a pump assist system, the method comprising:

directing a first conduit into the left side of the heart,

coupling a second conduit in fluid communication with a superficial artery of the patient,

connecting a pump between the first and second conduits,

implanting the pump within the patient,

suctioning blood from the left side of the heart through the first conduit and into the pump, and

expelling the blood from the pump into the second conduit and the superficial artery.

12. A system for supplementing blood flow from the heart of a patient, the system comprising:

a first conduit configured to be directed transeptally into the left side of the heart,

a second conduit configured to be coupled for fluid communication with a superficial artery of the patient, and

a pump configured to be superficially implanted within the patient and connected with the first and second conduits to suction blood from the first conduit and expel blood into the second conduit.

13. The system of claim 12, further comprising:

a transcutaneous power supply having a first portion implantable within the patient and a second portion adapted to be outside the body of the patient and capable of transferring power transcutaneously to the first portion, and

a pad having adhesive on a first side for adhering to the skin of the patient and having a first aligning and connecting member on a second side,

wherein the second portion further includes a second aligning and connecting member configured to engage and mate with the first aligning and connecting member to prevent misalignment between the first and second aligning and connecting portions.

14. The system of claim 12, further comprising:

a third conduit,

a fourth conduit, and

a second pump connected with the first pump and operatively coupled to the third and fourth conduits for suctioning blood from the third conduit and expelling the blood into the fourth conduit.

15. The system of claim 12, wherein the first conduit includes first and second branches, said first branch being configured to suction blood from the left side of the heart and said second branch being configured to suction blood from a superficial vein.

16. The system of claim 12, further comprising:

a return conduit coupled with an outlet of said pump for returning a portion of blood expelled from said pump to internal portions of said pump.

17. The system of claim 12, further comprising:

a return conduit coupled with an outlet of said pump for returning a portion of blood expelled by said pump from the return conduit to another portion of said system.

18. A system for supplementing blood flow from the heart of a patient, the system comprising:

a first conduit configured to be directed into the left side of the heart,

a second conduit configured to be coupled for fluid communication with an artery of the patient,

a pump configured to be implanted within the patient and connected with the first and second conduits to suction blood from the first conduit and expel blood into the second conduit, and

a return conduit coupled with an outlet of said pump for returning a portion of blood expelled by said pump from the return conduit to another portion of said system.

19. A transcutaneous power supply for use in providing electrical power to an implanted device within a patient, the power supply comprising:

a first portion implantable within the patient and a second portion adapted to be outside the body of the patient and capable of transferring power transcutaneously to the first portion,

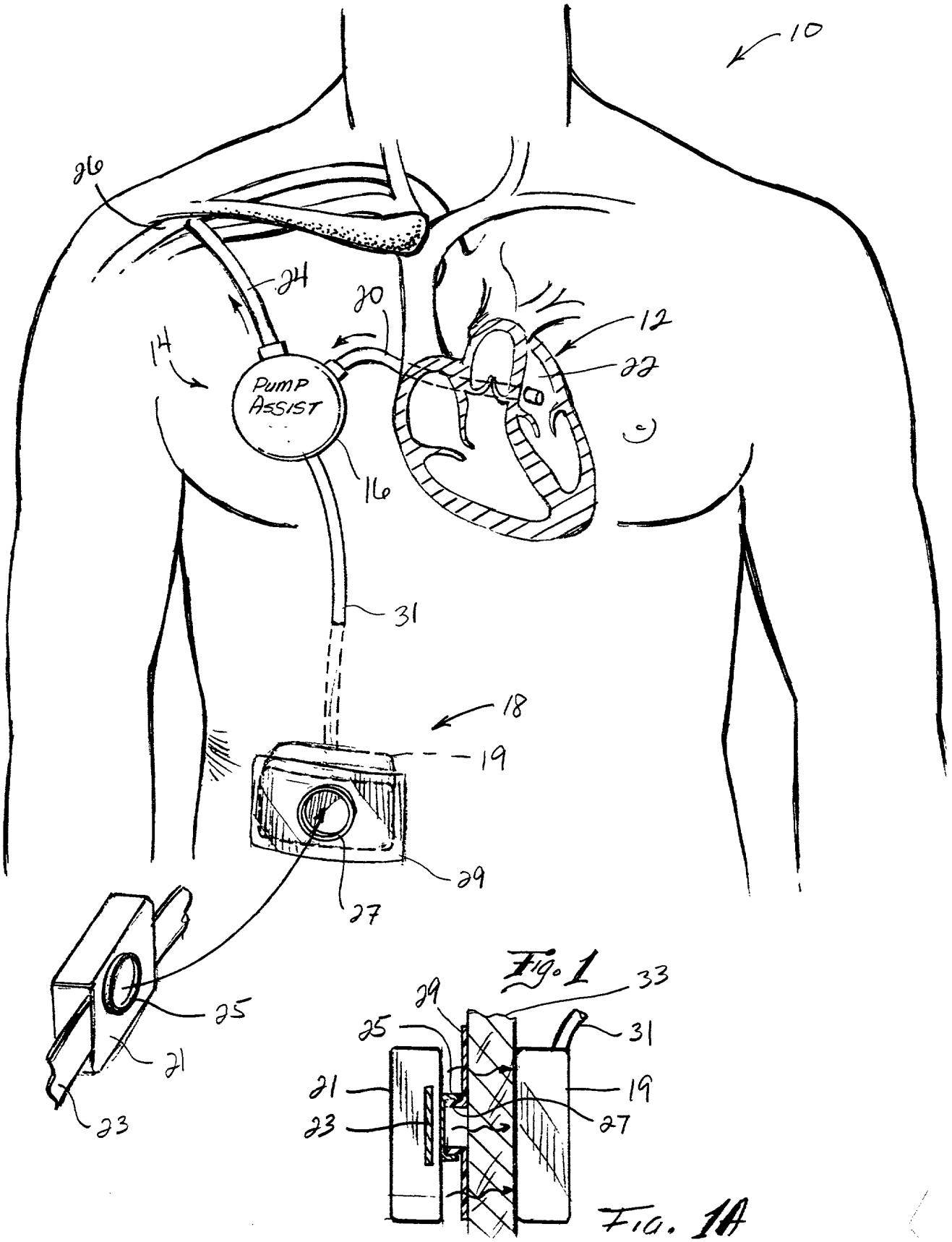
a pad having adhesive on a first side for adhering to the skin of the patient and having a first aligning and connecting member on a second side, and

a second aligning and connecting member on the second portion configured to engage and mate with the first aligning and connecting member to prevent misalignment between the first and second aligning and connecting portions.

SUPPLEMENTAL HEART PUMP METHODS AND SYSTEMS FOR SUPPLEMENTING BLOOD THROUGH THE HEART

Abstract of the Disclosure

Systems and methods of supplementing blood flow from the heart of a patient involving superficial, non-invasive procedures. In one general method, a first conduit is directed into the left side of the heart, a second conduit is directed into a superficial vessel and a pump is connected between the first and second conduits. The pump is implanted superficially in the patient and a power supply is connected to the pump. Blood is then suctioned from the left side of the patient's heart through the first conduit into the pump and expelled from the pump into the second conduit and the superficial vessel. A transcutaneous power supply is disclosed in one aspect and includes an external portion with a connection and alignment feature to assure reliable transmission of power.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PUMP ASSIST
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Fig. 1

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Fig. 1A

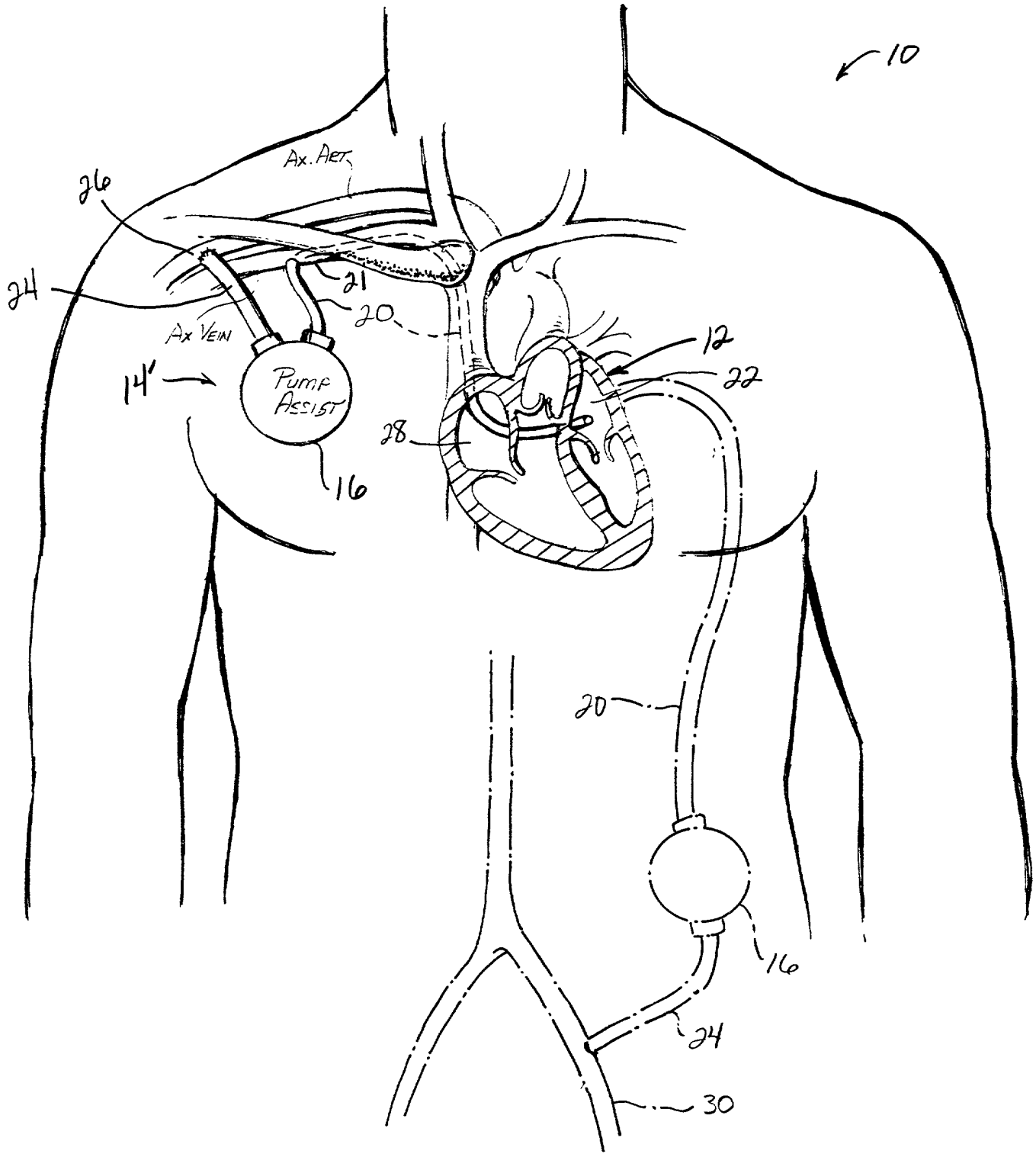


Fig. 2

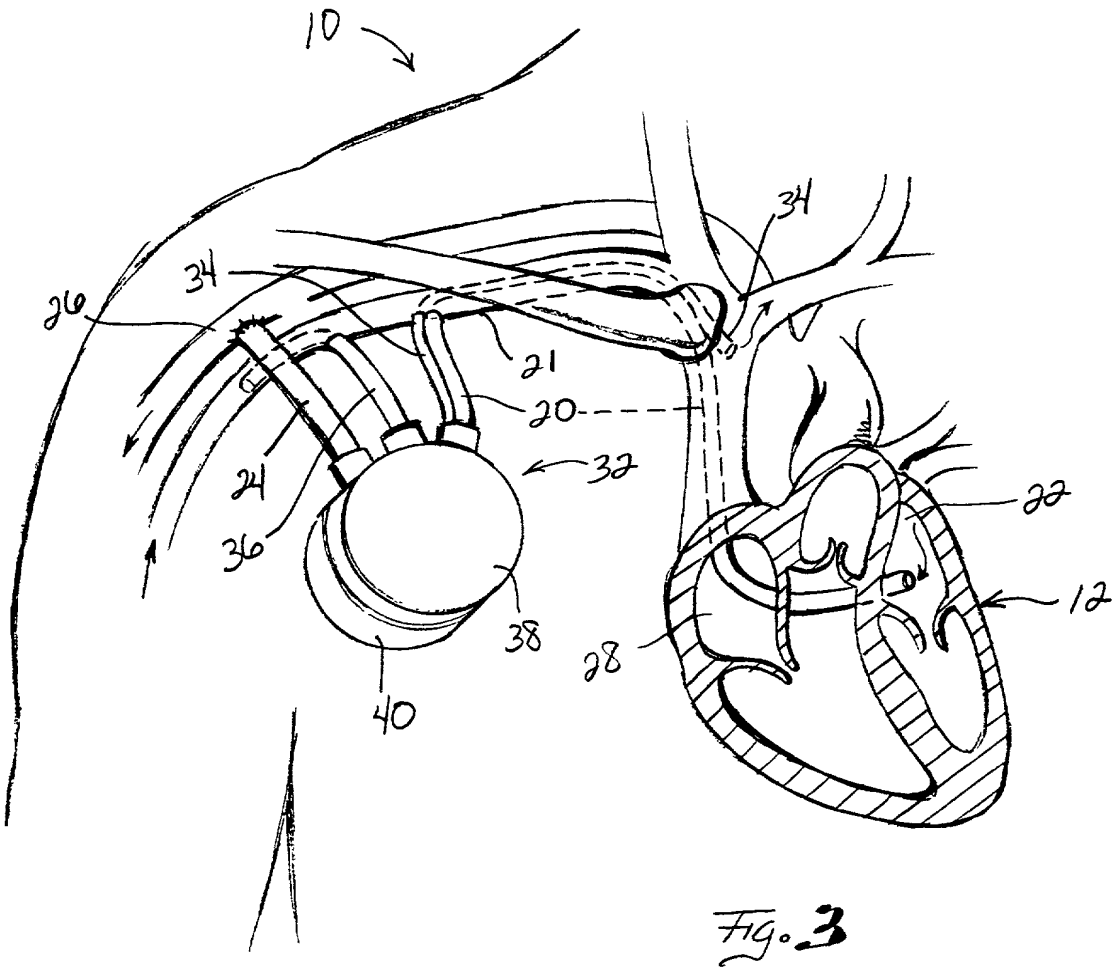


Fig. 3

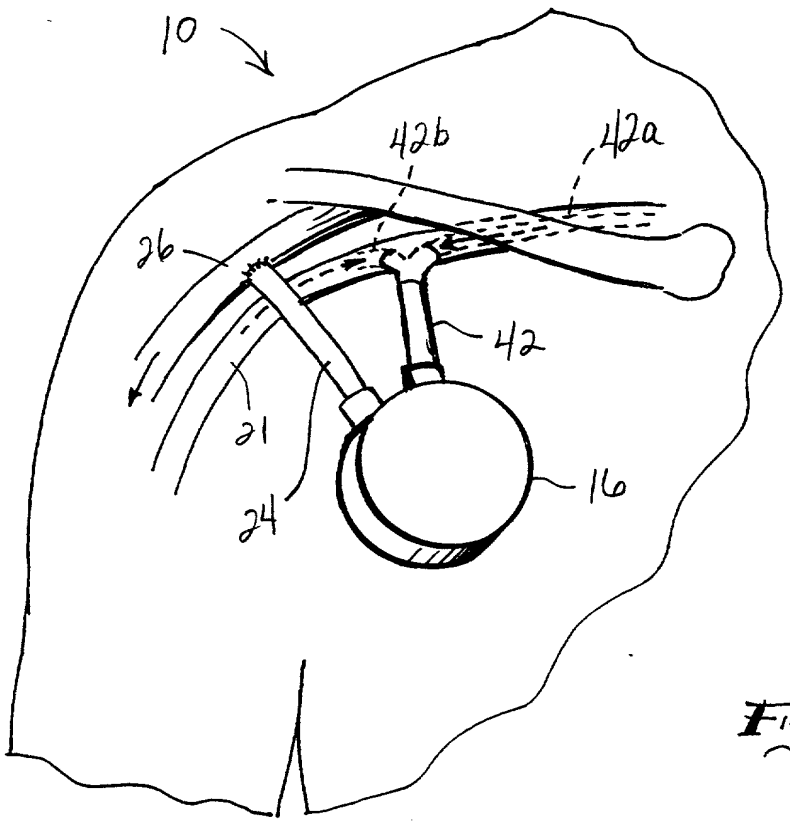
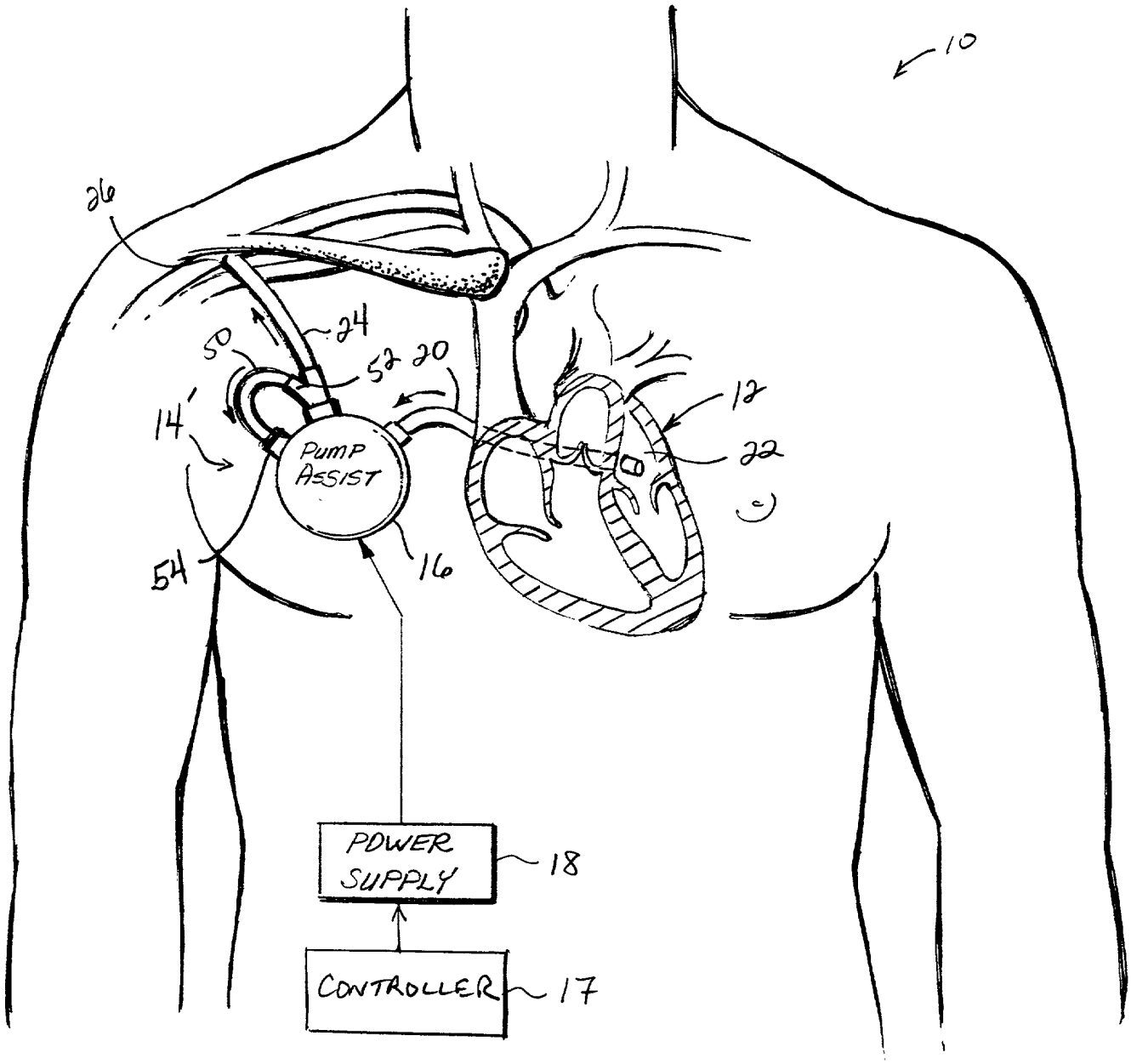


Fig. 4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PUMP ASSIST
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POWER SUPPLY
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CONTROLLER
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Fig. 5

DECLARATION, POWER OF ATTORNEY, AND PETITION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SUPPLEMENTAL HEART PUMP METHODS AND SYSTEMS FOR SUPPLEMENTING BLOOD THROUGH THE HEART

the specification of which (check one below):

(XX) is attached hereto.

(__) was filed on _____ as Application Serial No. _____ or Express Mail No. _____, Serial No. not yet known, and was amended on _____ (if applicable).

(__) was filed on _____ as PCT International Application No. _____ , and as amended under PCT Article 19 on _____ (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)
Priority Claimed

(Number)	(Country)	Day/Month/Year Filed	( ) Yes ( ) No
(Number)	(Country)	Day/Month/Year Filed	( ) Yes ( ) No
(Number)	(Country)	Day/Month/Year Filed	( ) Yes ( ) No

I hereby claim the benefit under Title 35, United States Code, §120 and/or §119(e) of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations §1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Serial No.)	(Filing Date)	(Status: Patented, Pending, or Abandoned)
(Serial No.)	(Filing Date)	(Status: Patented, Pending, or Abandoned)
(Serial No.)	(Filing Date)	(Status: Patented, Pending, or Abandoned)

I hereby appoint John D. Poffenberger (R. No. 20,245), Bruce Tittel (R. No. 22,324), Donald F. Frei (R. No. 21,190), David J. Josephic (R. No. 22,849), A. Ralph Navaro, Jr. (R. No. 23,050), David S. Stallard (R. No. 25,930), J. Robert Chambers (R. No. 25,448), Gregory J. Lunn (R. No. 29,945), Kurt L. Grossman (R. No. 29,799), Clement H. Luken, Jr. (R. No. 32,742), Thomas J. Burger (R. No. 32,662), Gregory F. Ahrens (R. No. 32,957), Wayne L. Jacobs (R. No. 35,553), Kurt A. Summe (R. No. 36,023), Kevin G. Rooney (R. No. 36,330), Keith R. Haupt (R. No. 37,638), Theodore R. Remaklus (R. No. 38,754), Thomas W. Humphrey (R. No. 34,353), Joseph R. Jordan (R. No. 25,686), C. Richard Eby (R. No. 25,854), David E. Pritchard (R. No. 38,273), David H. Brinkman (R. No. 40,532), J. Dwight Poffenberger, Jr. (R. No. 35,324), Beverly A. Lyman, Ph.D. (R. No. 41,961), A. Ralph Navaro III (R. No. P-46,207), Scott A Stinebruner (R. No. 38,323), Kristi L. Davidson (R. No. 44,643), P. Andrew Blatt, Ph.D. (R. No. 44,540) and David E. Franklin (R. No. 39,194), and of counsel, Herbert C. Brinkman (R. No. 16,955), all of Wood, Herron & Evans, L.L.P. 2700 Carew Tower, Cincinnati, Ohio 45202,

Telephone No. 513-241-2324, my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith. Address all correspondence and telephone calls to Kevin G. Rooney at Wood, Herron & Evans, L.L.P., 2700 Carew Tower, Cincinnati, Ohio, 45202 at telephone number (513) 241-2324.

Wherefore I pray that Letters Patent be granted to me for the invention or discovery described and claimed in the foregoing specification and claims, and I hereby subscribe my name to the foregoing specification and claims, declaration, power of attorney, and this petition.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor
(given name, family name) Paul A. Spence

Inventor's signature Paul Spence Date April 21/00

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